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To: Examiner E. Slobodyansky From: Cheryl H. Agris

Fax: 1-703-872-9306 Pages: 10

Phone: Date: 6/5/04

Re: 10/608,463 (JR-10003-US) CC:

☐ Urgent ☒ For Review ☐ Please Comment ☐ Please Reply

• **Comments:**

See attached - cert. fax transmission + response to restriction requirement

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JR-10,003-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ryan

Serial No.:10/608,463 Group Art Unit: 1652

Filed: June 27, 2003 Examiner: E. Slobodyansky

FOR: ISOLATED GENOMIC POLYNUCLEOTIDE FRAGMENTS FROM CHROMOSOME 12 THAT ENCODE HUMAN CARBOXYPEPTIDASE M AND THE HUMAN MOUSE DOUBLE MINUTE 2 HOMOLOG

Confirmation No.: 6428

CERTIFICATE OF FACSIMILE TRANSMISSION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence comprising:

1. Response to Restriction Requirement

was sent to the United States Patent Office by telefax to the attention of Examiner at fax number (703) **872-9306.**

Respectfully submitted,

Date: 6/5/04

Cheryl H. Agris

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JR-10,003-US PATENT

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Confirmation No.: 6428

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Restriction Requirement dated May 6, 2004, please consider the following remarks.

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CLAIM AMENDMENTS

1. (amended) An isolated genomic ~~polynucleotide~~nucleic acid molecule, said ~~polynucleotide~~ nucleic acid molecule obtainable from human chromosome 12q13-q15 region having a nucleotide sequence at least 95% identical to a sequence selected from the group consisting of:

(a) a genomic ~~polynucleotide~~ nucleic acid molecule encoding a polypeptide selected from the group consisting of human carboxypeptidase M depicted in SEQ ID NO:1 or human mouse double minute 2 homolog depicted in SEQ ID NO:2, or variants of SEQ ID NOS:1 or 2,

(b) a genomic ~~polynucleotide~~ nucleic acid molecule selected from the group consisting of SEQ ID NO:3 which encodes human carboxypeptidase M depicted in SEQ ID NO:1 and SEQ ID NO:4 which encodes human mouse double minute 2 homolog depicted in SEQ ID NO:2, or variants of SEQ ID NOS: 3 or 4;

(c) a ~~polynucleotide~~ nucleic acid molecule which hybridizes to any one of the ~~polynucleotides~~ nucleic acid molecules specified in (a)-(b)

(d) a ~~polynucleotide~~ nucleic acid molecule that is a reverse complement of the ~~polynucleotides~~ nucleic acid molecules specified in (a) – (c).

2. (amended) A nucleic acid construct comprising the ~~polynucleotide~~ nucleic acid molecule of claim 1.

3. (amended) An expression vector comprising the ~~polynucleotide~~ nucleic acid molecule of claim 1.

4. (amended) A recombinant host cell comprising the ~~polynucleotide~~ nucleic acid molecule of claim 1.

5. (amended) A method for obtaining a polypeptide encoded by a ~~polynucleotide~~ nucleic acid molecule obtainable from human chromosome 12, said polypeptide selected from the group consisting of human carboxypeptidase M and human mouse double minute 2 homolog comprising:

(a) culturing the recombinant host cell of claim 4 under conditions that provide for the expression of said polypeptide and

(b) recovering said expressed polypeptide.

6. (original) A method for preparing an antibody specific to a polypeptide selected from the group consisting of human carboxypeptidase M and human mouse double minute 2 homolog comprising:

(a) obtaining a polypeptide according to the method of claim 5;

(b) optionally conjugating said polypeptide to a carrier protein;

(c) immunizing a host animal with said polypeptide or polypeptide-carrier protein conjugate of step (b) with an adjuvant and

(d) obtaining antibody from said immunized host animal.

7. (amended) An isolated nucleic acid molecule or reverse complement thereof at least 20 nucleotides in length comprising a sequence of nucleotides which specifically hybridizes to a non-coding region of ~~SEQ ID NO:3 or 4~~the nucleic acid molecule of claim 1, which non-coding region is selected from the group consisting of an intron, a splice junction, a 5'- non-coding region, an expression control sequence, a transcription factor binding region and a 3'-non-coding region.

8. (amended) A method of diagnosing a pathological condition or susceptibility to a pathological condition in a subject comprising:

(a) isolating genomic DNA from a subject;

(b) determining the presence or absence of a variant in said genomic DNA using the ~~polynucleotide~~ nucleic acid molecule of claim 7;

(c) diagnosing a pathological condition or a susceptibility to a pathological condition based on the presence or absence of said variant.

9. (amended) A composition comprising the ~~polynucleotide~~ nucleic acid molecule of claim 1 and a carrier.

10. (amended) A composition comprising the ~~polynucleotide~~ nucleic acid molecule of claim 7 and a carrier.

11. (amended) A method for modulating levels of human carboxypeptidase M or human mouse double minute 2 homolog in a subject in need thereof comprising administering to said subject an amount of the ~~polynucleotide~~ nucleic acid molecule of claim 1 effective to modulate said human carboxypeptidase M or human mouse double minute 2 homolog

levels.

12. (amended) A method for modulating levels of human carboxypeptidase M or human mouse double minute 2 homolog in a subject in need thereof comprising administering to said subject an amount of the ~~polynucleotide~~ nucleic acid molecule of claim 7 effective to modulate said human carboxypeptidase M or human mouse double minute 2 homolog levels.

13. (amended) A method for preventing, treating or ameliorating a medical condition, comprising administering to a subject an amount of the ~~polynucleotide~~ nucleic acid molecule of claim 1 effective to prevent, treat or ameliorate said medical condition.

14. (amended) A method for preventing, treating or ameliorating a medical condition, comprising administering to a subject an amount of the ~~polynucleotide~~ nucleic acid molecule of claim 7 effective to prevent, treat or ameliorate said medical condition.

15. (amended) A kit comprising the ~~polynucleotide~~ nucleic acid molecule of claim 7.

16. (amended) The kit according to claim 15, in which the ~~polynucleotide~~ nucleic acid molecule is labeled with a detectable substance.

17. (amended) A solid support comprising the nucleic acid molecule of claim 7.

18. (original) The solid support of claim 17 wherein said support is a microarray.

19. (amended) The solid support of claim 18, wherein said microarray further comprises a plurality of nucleic ~~acids~~ acid molecules hybridizing to a non-coding region of SEQ ID NO3 or 4.

20. (amended) The solid support of claim 18, wherein said microarray further comprises a nucleic acid molecule encoding human carboxypeptidase M and/or human mouse double minute 2 homolog or a portion thereof.

21. (amended) ~~A polynucleotide~~The nucleic acid molecule of claim 1 comprising:

(a) a genomic double stranded ~~polynucleotide~~ nucleic acid molecule set forth in SEQ ID NO:3 encoding human carboxypeptidase M set forth in SEQ ID NO:1 and the

~~polynucleotide~~ nucleic acid molecule set forth in SEQ ID NO:4 encoding human mouse double minute 2 homolog set forth in SEQ ID NO:2;

(b) a ~~polynucleotide~~ nucleic acid molecule that hybridizes to one strand of the ~~polynucleotide~~ nucleic acid molecule of (a) and

(c) a reverse complement of (a) and (b).

22. (amended) A method of identifying variants of SEQ ID NO:3 and SEQ ID NO:4 comprising

(a) isolating genomic DNA from a subject and

(b) determining the presence or absence of a variant in said genomic DNA using the ~~polynucleotide~~ nucleic acid molecule of claim 7.

REMARKS

Claims 1-22 are pending in the above-referenced application. Claims 1-5 and 7-22 have been amended to more distinctly claim that which Applicants regard as their invention. No new matter has been added.

Restriction is required to one of the following groups:

I. Claims 1-5, 21 (all in part), drawn to a polynucleotide encoding carboxypeptidase M of SEQ ID NO: 1, including SEQ ID N0:3, a vector containing it, a host cell transformed with the same and a method of making carboxypeptidase M, classified in class-435, subclass 226.

II. Claims 1-5, 21 (all in part), drawn to a polynucleotide encoding human mouse double minute 2 homolog of SEQ ID NO: 2, including SEQ ID N0:4, a vector containing it, a host cell transformed with the same and a method of making human mouse double minute 2 homolog, classified in class 435, subclass 226.

III. Claim 6 (in part), drawn to a method of making an antibody against carboxypeptidase M, classified in class 424, subclass 185.1.

IV. Claim 6 (in part), drawn to a method of making an antibody against human mouse double minute 2 homolog, classified in class 424, subclass 185.1.

V. Claims 7, 9, 10 and 15-20 (all in part), drawn to a nucleic acid of a non-coding region of SEQ ID NO: 3, a composition, a kit and a solid support comprising thereof, classified in class 536. subclass 74 1

VI. Claims 7, 9, 10 and 15-20 (all in part), drawn to a nucleic acid of a non-coding region of SEQ ID NO: 4, a composition, a kit and a solid support comprising thereof, classified in class 536, subclass 24.1.

VII. Claims 11 and 13 (both in part), drawn to methods of treating a subject with a polynucleotide encoding carboxypeptidase M of SEQ ID NO: 1, classified in class 514, subclass 44.

VIII. Claims 11 and 13 (both in part), drawn to methods of treating a subject with a polynucleotide encoding human mouse double minute 2 homolog of SEQ ID NO: 2, classified in class 514, subclass 44.

IX. Claims 12 and 14 (both in part), drawn to methods of treating a subject with a nucleic acid of a non-coding region of SEQ ID NO: 3, classified in class 514, subclass 44.

X. Claims 12 and 14 (both in part), drawn to methods of treating a subject with a nucleic acid of a non-coding region of SEQ ID NO: 4, classified in class 514, subclass 44.

XI. Claims 8 and 22 (both in part), drawn to a method of identifying variants of SEQ ID NO: 3, classified in class 435, subclass 6.

XII. Claims 8 and 22 (both in part), drawn to a method of identifying variants of SEQ ID NO: 4, classified in class 435, subclass 6.

In order to be completely responsive, Applicant hereby elects with traverse the claims in Group VI, drawn to a nucleic acid of a non-coding region of SEQ ID NO: 4, a composition, a kit and a solid support comprising thereof. However, Applicant reserves the right to file subsequent continuation and/or divisional applications on nonelected subject matter. Applicant asserts that it is not necessary to elect a species since Group VI is drawn to SEQ ID NO:4.

At the very least, groups II, IV, VI, VIII, X and XII should be examined together. This is because of the linking claims 7, 8, 11, 13 and 22. As noted above, claim 7 now depends from claim 1. It is Applicant's position that claim 7 and claim 1 constitute the same invention. This is because claim 7 is merely directed to a sequence hybridizing to a non-coding region of claim 1. However, even assuming *arguendo* that claim 1 and claim 7 are different inventions, they should be examined together because they are linked together. As noted above, other linking claims include claims 8, 11, 13, and 22. According to MPEP §809:

> The linking claims must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn. Any claim directed to the nonelected invention(s) previously withdrawn from consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability. Where such withdrawn claims have been canceled by applicant pursuant to the restriction requirement, upon the allowance of the linking claim(s), the examiner must notify applicant that any canceled, nonelected claim(s) which depends from or includes all the limitations of the allowable linking claim may be reinstated by submitting the claim(s) in an amendment. Upon entry of the amendment, the amended claim(s) will be fully examined for patentability.

It is also Applicant's position that it is unnecessary to examine SEQ ID NO:3 and 4 separately. This is because only two sequences involved and their proximity to each other. Specifically, the two sequences are located in the human chromosome 12q13-q15 region and are contiguous. Thus it would not constitute an undue burden to search both of these sequences.

In view of the foregoing, Applicant respectfully requests reconsideration of the Restriction Requirement. Applicant asserts that the claims are now in condition for examination. Early action to that end is respectfully requested. The Examiner is invited to contact the undersigned at (914) 712-0093 if she has any questions.

Respectfully submitted,

Date: 6/5/04

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